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EXAMINER	
STUCKER, J	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 21

Application Number: 08/487355
Filing Date: 6/7/95
Appellant(s): Bolognesi et al.

Laura A. Coruzzi
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed 12/11/98.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the

pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

The newly submitted abstract of the disclosure is acceptable and has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 17 and 20-55 will stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 17 and 20-50 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has shown in the specification that some particular peptides from a few examples can have some effect. This cannot be extended broadly to any peptide from any virus. The mechanism of infection from each of the many possible viruses that can be included in the search motif is so broad that one would have to engage in an undue amount of experimentation to find particular peptides from particular viruses that would have the desired effect. There is no guidance in the specification as to which proteins or peptides that are included in the immense number of peptides which fall within the search motifs that would inhibit viral infection. This is particularly true as each virus is different and would have a different mode of infection. A showing of the effectiveness of some peptides from HIV, for example, would not be a suitable showing of efficacy for hypothetical peptides from hepatitis B virus. The mode of action of the peptides is by applicant's own admission not known, and would therefore, exclude an expectation of success based on even a hypothetical mode of action. Each of the viruses in the specification are different from each other, have different routes of infection, different phylogenies, etc. Further, the specification teaches on page 340, lines 7-13 that "the antiviral activity of the peptides of the invention may show a pronounced

type and subtype specificity, i.e., specific peptides may be effective in inhibiting the activity of only specific viruses." One would not expect the instant method to transfer from one virus to another absent some working examples of peptides from the claimed virus. Therefore, the instant specification does not provide and enabling disclose for the invention as claimed.

Claims 17 and 20-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting cell fusion, does not reasonably provide enablement for "inhibiting transmission" or "neutralizing hepatitis B virus". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Assuming arguendo that one would expect a given hepatitis B peptide to have an antiviral effect, the specification is not enabled for methods for "inhibiting transmission" or "neutralizing hepatitis B virus". The only disclosed antiviral activity taught in the specification is for inhibiting cell fusion between uninfected and infected cells *in vitro* by direct treatment with a peptide. The mode of action of the peptides in the instant method is unknown. One can not say with confidence that the peptides can "neutralize" a virus or "inhibit" the transmission of the virus. The claim language implies specific direct activity against the virus. The only teaching in the specification at best is inhibition of cell fusion.

The specification, while enabled for *in vitro* methods, is not enabled for *in vivo* methods even if one were to have an expectation of success that a given hepatitis B peptide will have an antiviral effect. The specification teaches the use of some peptides in a static *in*

vitro system while providing no guidance for using the claimed method in a dynamic *in vitro* system. A living body is extremely complex and unpredictable. Therefore, the instantly disclosed invention is not enabled for *in vivo* uses. Further, the specification is not enabled for antiviral activity by inducing an immune response. There is no evidence that an immune response, if induced would have an antiviral effect. The specification teaches the use of peptides, not anti-peptide antibodies which are several steps removed from the peptides themselves. Thus, the instant specification is not enabled for the scope of the claimed invention.

(11) Response to Argument

The enablement rejection was originally made as two rejections but during the course of prosecution, they became melded into a single rejection. The response will follow this pattern and address all of the remaining issues.

Applicant argues that the claimed method uses specific peptides to inhibit transmission of hepatitis B virus to cells. Applicant argues that each of the identified peptides has been defined by one of the computer search motifs of the invention which have been shown to identify peptides which exhibit antiviral activity. Applicant posits that these peptides are shown to inhibit viral infection of cells through routine assays. Applicant further argues that the *in vitro* assays discussed in the application reflect anti-viral activity *in vivo* including inhibition of viral transmission to cells. Applicant premised this on the activity of the HIV

specific DP178 peptide. Because the instant peptides are discovered by a computer search motif, they must have the same activity as DP107/178.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Section 22, pages 390-391, discloses that a search motif was applied to the hepatitis sequence to discover peptides which matched the motif. This section of the specification does not predict or demonstrate that the claimed peptides have anti-viral effect. Page 391, lines 14-21, states that the activity of the peptides is tested by various known methods. This is not convincing as there is no data supplied for these tests, only assertions that this "is" done. This can be read to mean that this is a known way to test for desired activity. It is not clear if the tests were actually performed or are disclosed as possible methods for ascertaining the activity of the computed peptides. Applicant has not provided evidence that these tests showed any anti-hepatitis activity, and if so, how any activity correlates to *in vivo* efficacy. Applicant has not taught how to make and use the claimed invention in such a way so as to overcome the difficulties of moving from an *in vitro* model to a dynamic *in vivo* body. The reliance upon the antiviral data of DP107/178 peptides as models of antiviral activity is not convincing. The DP107/178 peptides have anti-HIV as documented by the data in the specification. However, this is not transferable to hepatitis because HIV is very different from hepatitis. HIV is RNA retrovirus with trophism for lymphocytes whereas hepatitis is a double stranded DNA virus that infects the liver. The viruses attack different tissues, cause different diseases, and attach to different cellular receptors. Applicant has provided extensive data on the anti-HIV effects of the DP107/178 peptides but has not shown anti-hepatitis activity of the DP107/178 peptides

nor any anti-hepatitis activity of the claimed peptides. A showing of the efficacy of DP107/178 peptides against HIV fusion is not convincing that the instantly claimed peptides will have anti-hepatitis activity given the vast differences between the viruses and the lack of data that the instantly claimed peptides have the claimed activity. Therefore, the instant specification does not provide an enabling disclosure for the invention as claimed.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

JEFFREY STUCKER
PRIMARY EXAMINER

JS
January 28, 1999

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